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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|-------------------|----------------------|---------------------|------------------|
| 09/939,921 | 08/27/2001 | Mark L. Chivers | 11916.0042.DVUS01 | 5294 |
| | 7590 01/05/2004 | | EXAM | INER |
| Matthew L. Madsen | | | BORIN, MICHAEL L | |
| HOWREY SI | MON ARNOLD & WHIT | re, llp | | |
| 750 Bering Drive | | | ART UNIT | PAPER NUMBER |
| Houston, TX 77057-2198 | | | 1631 | |

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

| Application N . | Applicant(s) |
|-----------------|----------------|
| 09/939,921 | CHIVERS ET AL. |
| Examiner | Art Unit |
| Michael Borin | 1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

| | statute, cause the application to become ABANDONED (35 U.S.C. § 133). mailing date of this communication, even if timely filed, may reduce any |
|--|--|
| Status | |
| 1) Responsive to communication(s) filed on | <u>09 October 2003</u> . |
| 2a) This action is FINAL . 2b) 2 | This action is non-final. |
| | owance except for formal matters, prosecution as to the merits is der <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |
| Disposition of Claims | |
| 4)⊠ Claim(s) <u>36-55</u> is/are pending in the applic | cation. |
| 4a) Of the above claim(s) is/are with | ndrawn from consideration. |
| 5) Claim(s) is/are allowed. | |
| 6) Claim(s) is/are rejected. | |
| 7) Claim(s) is/are objected to. | |
| 8) Claim(s) 36-55 are subject to restriction are | nd/or election requirement. |
| Application Papers | |
| 9)☐ The specification is objected to by the Exa | |
| 10)☐ The drawing(s) filed on is/are: a)☐ | accepted or b) objected to by the Examiner. |
| Applicant may not request that any objection to | the drawing(s) be held in abeyance. See 37 CFR 1.85(a). |
| Replacement drawing sheet(s) including the co | prrection is required if the drawing(s) is objected to. See 37 CFR 1.121(d). |
| 11)☐ The oath or declaration is objected to by th | e Examiner. Note the attached Office Action or form PTO-152. |
| Priority under 35 U.S.C. §§ 119 and 120 | |
| 12) Acknowledgment is made of a claim for fo a) All b) Some ★ c) None of: | reign priority under 35 U.S.C. § 119(a)-(d) or (f). |
| 1. Certified copies of the priority docum | |
| | nents have been received in Application No priority documents have been received in this National Stage |
| * See the attached detailed Office action for a | |
| 13) Acknowledgment is made of a claim for don since a specific reference was included in the | nestic priority under 35 U.S.C. § 119(e) (to a provisional application) e first sentence of the specification or in an Application Data Sheet. |
| 37 CFR 1.78. | |
| a) The translation of the foreign language | e provisional application has been received. nestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific |
| | of the specification or in an Application Data Sheet. 37 CFR 1.78. |
| Attachment(s) | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary (PTO-413) Paper No(s) |

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)

6) Other:

Notice of Informal Patent Application (PTO-152)

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DETAILED ACTION

Status of Claims

Response and amendment filed 10/09/2003 are acknowledged.

Claims 36, 40 are amended. Claims 53-55 are added. Claims 36-55 are pending.

Examiner apologizes for inadvertent error in applying references teaching somatostatin, rather than somatotropin, in art rejections of record. The art rejections are withdrawn; new appropriate rejections will be applied in the next, non-final, Office action.

Prior to the Office action, the following restriction requirement is deemed to needed in view of amendment to the claims:

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 36-39,43-52, drawn to compositions comprising somatotropin and polyacrylamide, classified in class 514, subclass 772.3.
- II. Claims 40-42,53-55, drawn to compositions comprising somatotropin and polysaccharide, classified in class 514, subclasses 777,778, 781.

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Groups I and II are patentably distinct as their composition is different in regard to the anionic polymer, which is defined in terms of density (and, further, as being polyacrylamide) in group I as opposed to being a polysaccharide in Group II. Being an "anionic polymer" is not a sufficient common core structure needed for common utility. Further, the Groups have different enablement requirements and require separate search due to their different classification.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

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Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 19, 2003

mlb

MICHAEL BORIN, PH.D. PRIMARY EXAMINER